REMARKS

Claim status

Claims 1, 3-5, 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62, and 64 were pending in the case at the time of the current Office Action. No claims are amended herein. Claims 1, 3-5, 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45-47, 49-52, 54-57, 59-62, and 64 are currently pending in the application.

Section 102 rejections

In the current Office action, claims 1, 3-5, 46, and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Prutchi et al. (US 6,141,585), hereinafter Prutchi.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites a device for delivering electrical stimulation pulses to body tissue through a stimulation electrode, comprising:

energy storage means for providing electrical stimulation energy to the stimulation electrode from an energy source;

a first switch with which the energy storage means is switchably connected to the energy source for charging the energy storage means;

an electrode connection for connecting the stimulation electrode to the device for delivering electrical stimulation pulses to the body tissue;

a second switch with which the energy storage means is switchably connected to the electrode connection for the delivery of a stimulation pulse;

means for monitoring stimulation outcome;

a short-circuit switch with which the electrode connection, after delivery of the stimulation pulse, is switchably and at least indirectly connected to a ground potential such that,

in the case of a connected and implanted electrode, a capacitance can be discharged by way of the body tissue wherein the capacitance includes at least one Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue; and

a control unit which is connected to at least the first switch, the second switch, and the short-circuit switch for switching the respective switches and which is adapted to separate the electrode connection from the energy storage means after delivery of the stimulation pulse and at least indirectly connect the electrode connection to the ground potential;

wherein the means for monitoring stimulation outcome, at least after delivery of a stimulation pulse, is connected to the electrode connection and is adapted to detect a drop in a voltage over time at the capacitance or a rise in a short-circuit current over time at the capacitance, said drop in voltage or said rise in short-circuit current being representative of a characteristic drop in a myocardium impedance of said body tissue indicating stimulation success.

The claimed invention of claim 1 is directed to a device that detects a drop in a voltage or a rise in a short-circuit current over time at a capacitance that includes at least one Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue. The drop in voltage or the rise in short-circuit current over time is representative of a characteristic drop in a myocardium impedance over time, indicating stimulation success. With the claimed invention of claim 1, a short term drop in the impedance of the myocardium itself is detected. In order to measure such short term drop of impedance, a current or a voltage source is used which is readily available immediately after delivery of the stimulation pulse. According to the claimed invention, a capacitor that is in the short cut circuit (from the myocardium to ground potential) during autoshort after delivery of a stimulation pulse is used as a current or a voltage source. The short term drop of myocardial impedance is detected by evaluating a time course of a voltage or a current over a capacitance in the short cut circuit. This capacitance can be a coupling capacitor, a Helmholz capacitance, or a combination

of both, or any other capacitance in the short cut circuit as would be apparent to one skilled in the art. One skilled in the art knows that a load impedance can be determined by either analyzing a time course of a voltage when discharging a capacitor into a load, or a time course of a current, since it is the slope of the voltage or the current that characteristically depends on the load (impedance of the myocardium).

Prutchi does not teach or suggest detecting a drop in a voltage or a rise in a short-circuit current over time at a capacitance that includes at least one Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue. Instead, Prutchi describes an apparatus and methods to indicate the condition of the pacer leads as well as to estimate electric charge, current, and energy delivered to the heart tissue (column 3, lines 50-53). Prutchi further describes that such conditions include electrode micro-dislocation, lead impedance changes, evaluation of electrode suitability for detecting evoked potentials, and methods for detecting changes in the excitable tissue as a function of catecholamine concentration, metabolic changes, and ischemia. In addition, the charge, current, energy, and impedance measurements allow physicians to estimate the longevity of the implanted device (column 3, lines 55-63). Prutchi accomplishes this by measuring both of resistive and capacitive components of the lead impedance in order to improve the implementation of an implanted stimulation device (see column 4, lines 52-56). Prutchi gives no suggestion of using the device as an indication of capture detection (i.e., successful stimulation). Instead, Prutchi describes using the resistive and capacitive components of the lead impedance to help indicate the condition of the pacer leads as well as to estimate electric charge, current, and energy delivered to the heart tissue (see column 3, lines 49-53), and for optimizing parameters such as instantaneous current, average current, charge, and energy delivered to the cardiac tissue (see ABSTRACT).

In particular, Prutchi does not teach or suggest measuring a drop in a voltage or a rise in a short-circuit current over time at the Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue. Instead, Prutchi is making single sample and hold measurements, each at a single time. For example,

Prutchi describes that the output signals from sample-and-hold units U1, U2, and U3 represent voltages measured in the pulse generator (column 10, lines 40-42), not at the Helmholtz capacitance produced on the surface of the stimulation electrode in conjunction with surrounding body fluid or the body tissue. Also, U2 and U3 do not sample after the delivery of a stimulation pulse as in claim 1. U1 samples after the pacing pulse, but at the tank capacitor C_T within the pulse generator 468, not at the Helmholtz capacitance, and not over time but, instead, just at a single sample time T_{PW}^{+} (column 10, lines 48-50 and column 12, lines 39-43).

As a result, it should be understood that the impedance circuit 466 of Prutchi is not a means for monitoring stimulation outcome as in the claimed invention of claim 1. In claim 1, the means for monitoring stimulation outcome measures a voltage or a short-circuit current over time to characterize a drop in myocardium impedance over time. It should be clear that the impedance circuit 466 of Prutchi does not measure voltage or current over time as does the means of monitoring stimulation outcome of claim 1. Instead, the impedance circuit 466 of Prutchi simply samples a voltage at a single time during or after the pacing pulse. Furthermore, Prutchi does not teach or suggest that such a single sample could be used to indicate stimulation success. Applicants contend that the device of claim 1 is able to indicate stimulation success precisely because measurements are made over time after the stimulation pulse at the Helmholtz capacitance, which Prutchi does not teach or suggest.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not anticipated by Prutchi, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claims 3-5, 46 and 50-51 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 3-5, 46 and 50-51 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 1, 3-5, 46 and 50-51 under 35 U.S.C. 102(b) be removed.

Section 103 rejections

In the current Office action, claims 55-56 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prutchi.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above, it is respectfully submitted Prutchi does not teach or suggest the invention of independent claim 1. In particular, Prutchi does not teach or suggest a means for monitoring stimulation outcome, at least after delivery of a stimulation pulse, is connected to the electrode connection and is adapted to detect a drop in a voltage over time at the capacitance or a rise in a short-circuit current over time at the capacitance, said drop in voltage or said rise in short-circuit current being representative of a characteristic drop in a myocardium impedance of said body tissue indicating stimulation success.

Prutchi does not disclose how a means for monitoring stimulation outcome is able to determine, after delivery of stimulation, whether stimulation was effective or if, on the contrary, there was a loss of capture.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 is not unpatentable over Prutchi, and it is respectfully submitted that independent claim 1 defines allowable subject matter. Also, since claims 55-56 and 60-61 depend either directly or indirectly from claim 1, it is respectfully submitted that claims 55-56 and 60-61 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 55-56 and 60-61 under U.S.C. 103(a) be removed.

Allowable Subject Matter

In the current Office action, claims 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45, 47, 49, 52, 54, 57, 59, 62 and 64 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicants respectfully acknowledge and thank the Examiner for the above-mentioned allowable subject matter, however, Applicants believe that dependent claims 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45, 47, 49, 52, 54, 57, 59, 62 and 64 are allowable because they depend either directly or indirectly from independent claim 1 which Applicants have argued herein is allowable.

Applicants respectfully request that the objection to claims 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45, 47, 49, 52, 54, 57, 59, 62 and 64 be removed and that claims 8-17, 28, 30, 32, 34-35, 38-40, 42-43, 45, 47, 49, 52, 54, 57, 59, 62 and 64 be recognized as allowable in their present dependent form.

Accordingly, the applicant respectfully requests reconsideration of the rejections and objections based on at least the foregoing. After such reconsideration, it is urged that allowance of all pending claims will be in order.

Respectfully submitted,

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